

REMARKS

Election/Restrictions

Claims 10-16, 18, 19, 21, 27, 28, 30, 31, 33-39 and 56-72 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has chosen to maintain the withdrawn claims in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

Claim Rejections – 35 USC §102 and 103

Claims 3, 5-9, 17 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,306,309 to Wagner et al. (hereafter “the Wagner reference”). Claims 3, 4 and 17 rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0004660 to Henniges et al. (hereafter “the Henniges reference”). Claims 3-6, 8, 9 and 26 were rejected under 35 U.S.C. §102(a) or §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0093153 to Banick et al. (hereafter “the Banick reference”). Additionally, claims 22-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Banick reference in view of U.S. Patent No. 4,523,679 to Paikoff et al. (hereafter “the Paikoff reference”).

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent claim 3 has been amended to recite spinal implant components comprising “an elongate spinal plate member and a number of bone screws” configured to secure said elongate spinal plate member to first and second vertebrae. This amendment does not raise new issues that would require additional searching and/or consideration since these features were recited in dependent claim 4 which has already been examined. Dependent claim 4 has been cancelled without prejudice. Additionally, recitation of “spinal implant components” (as opposed to “a spinal implant”) was incorporated into independent claim 3 to improve its form to more accurately reflect the fact that more than one spinal component is included in the surgical

kit (e.g., a spinal plate and bone screws). Original dependent claim 22 also makes references to the inclusion of multiple spinal implant components.

Independent claim 3 has also been amended to recite that the instrumentation comprises a driver instrument “including an end portion configured to drivingly engage said bone screws into engagement with vertebral bone”. This amendment does not raise new issues that would require additional searching and/or consideration since these features were recited in dependent claim 17 which has already been examined.

Independent claim 3 has been further amended to recite that the packaging comprises a common container, with “said spinal implant assembly and said instrumentation integrally contained and sealed within said common container to maintain said spinal implant assembly and said instrumentation in a sterilized condition prior to the spinal surgery”. This amendment likewise does not raise new issues that would require additional searching and/or consideration since these features were recited in the previous version of independent claim 3. The Applicant has simply recited such features in a more positive manner to address the comment set forth on page 5 of the Office Action that the “adapted to” language “is indefinite, in that it is merely functional language”.

Dependent claims 5, 17, 19 and 22-26 have been amended in view of the amendments incorporated into independent base claim 3 and/or to improve their form. Additionally, withdrawn independent claims 10, 18 and 27 have been amended to depend from independent claim 3. Accordingly, withdraw claims 10, 18 and 27 would be subject to reinstatement upon the allowance of independent base claim 3.

The Wagner reference is directed to an interbody implant or disc 50 and an implant holder tool 100. However, the Wagner reference does not disclose or suggest a surgical kit including “an elongate spinal plate member and a number of bone screws” for securing the spinal plate to first and second vertebrae, in combination with “a driver including an end portion configured to drivingly engage said bone screws into engagement with vertebral bone”, and with the spinal components and the instrumentation integrally contained and sealed within a common container to maintain a sterilized condition prior to the spinal surgery. Indeed, the Wagner reference does not make any reference whatsoever to a spinal plate, bone screws or a driver

instrument for driving the bone screws into vertebral bone, nor that such components are integrally contained and sealed within a common container to maintain a sterilized condition prior to surgery. For at least these reasons, withdrawal of the rejection of independent claim 3 as being anticipated by the Wagner reference is respectfully requested.

Similar to the Wagner reference, the Banick reference is likewise directed to an interbody implant 20 and an implant holder tool 52. Furthermore, the Banick reference does not disclose or suggest a surgical kit including “an elongate spinal plate member and a number of bone screws” for securing the spinal plate to first and second vertebrae, in combination with “a driver including an end portion configured to drivingly engage said bone screws into engagement with vertebral bone”, and with the spinal components and the instrumentation integrally contained and sealed within a common container to maintain a sterilized condition prior to the spinal surgery. Indeed, the Banick reference does not make any reference whatsoever to a spinal plate, bone screws or a driver instrument for driving the bone screws into vertebral bone, nor that such components are integrally contained and sealed within a common container to maintain a sterilized condition prior to surgery. For at least these reasons, withdrawal of the rejection of independent claim 3 as being anticipated by the Banick reference is respectfully requested.

The Henniges reference appears to disclose a spinal plate 10, bone fasteners 12 and a driver tool 24. However, these devices are not “sealed within said common container to maintain said spinal implant assembly and said instrumentation in a sterilized condition prior to the spinal surgery”, as recited in independent claim 3. To the contrary, the Henniges reference discloses that these devices are individually packaged in separate containers.

Specifically, the plates 10 are contained in plate packaging (paragraphs 59 and 60), the fasteners 12 are contained in a separate container 76 (paragraph 79), and the driver 24 and other tools are contained within yet another separate instrument container (Figure 31). Indeed, there is no indication or suggestion that each of these devices are integrally contained and sealed within a common container to maintain a sterilized condition prior to spinal surgery, as substantially recited in amended independent claim 3. Instead of providing a self-contained, all inclusive kit which packages the spinal components (including the spinal plate and bone screws) and the screw driver within a common, sterilized container, the Henniges reference specifically teaches

that the components and instruments are packaged separately from one another in individual containers, which is directly contrary to the inventive concept recited in independent claim 3.

Indeed, the Henniges reference discloses specific features for ensuring that the appropriate plate 10 and fasteners 12 are selected from product inventory for a particular surgical procedure. Specifically, the Henniges reference discloses that various plates 10 are color coded for identification purposes to ensure selection of the appropriate plate for the surgical procedure. (“The plates 10 can come in several different sizes and shapes depending on the specific application. By manufacturing the plates 10 with a unique color associated with each unique shape and size, confusion will be minimized and time will be saved.”) (paragraph 59). Additionally, the Henniges reference discloses that “the package containing bioabsorbable plates 10 are marked with an identification mark, not shown. The mark allows the package with the plates 10 to be identified more precisely . . . in a manner that will allow the nurse or doctor to easily read and recognize the identification mark and the corresponding mark on the package containing the plate 10.” Likewise, “color coding of the fasteners 12 will allow easy and quick identification of different fasteners 12” to ensure selection of the appropriate fasteners for the surgical procedure. (Paragraph 67).

Accordingly, the Henniges reference fails to disclose or suggest the concept of providing a self-contained kit which integrally contains the spinal components and instrumentation necessary to perform a designated spinal surgical procedure within a common container in a sterilized container, as substantially recited in rewritten independent claim 3. Moreover, the Henniges reference seems to specifically teach away from this inventive concept, instead teaching that the plates 10 are contained within separate packages that are colored coded and individually marked to facilitate selection of an appropriate plate from product inventory, and that the fasteners 12 are likewise contained within separate packages that are colored coded and individually marked to facilitate selection of appropriate fasteners from product inventory.

The drawbacks and disadvantages associated with selecting surgical components and instruments from product inventory are specifically discussed in the background section of the subject application at page 1, line 18 to page 2, line 6. Specifically, the background section of the subject application sets forth the following:

Many different types and sizes of implants, devices and instruments are available for treating various diseases, pathologies, injuries or malformations affecting the spine. In the past, the components required for a spinal surgical procedure have been supplied individually to surgical facilities, such as hospitals, trauma or ambulatory centers, medical or research laboratories, and surgical training facilities. Relatively high levels of inventory have been procured and maintained to accommodate the varying requirements associated with a spinal surgical procedure (e.g., anatomical requirements that dictate the selection of a particular size and configuration of implant, device and/or surgical instrument).

As should be appreciated, high inventory levels are expensive to procure and maintain, and are subject to loss, damage and possible theft. Moreover, the cost of even the most basic of surgical instrumentation can be quite high. Additionally, the availability of implants, devices and surgical instrumentation may be scarce, particularly with regard to remote or under-represented surgical facilities. Cleaning, sterilizing and maintaining surgical components can be both time consuming and expensive, particularly with regard to surgical instrumentation that is designed for repeated use. Additionally, cleaning and sterilization procedures may result in significant wait or down time in cases involving back-to-back scheduling of multiple surgical procedures.

The drawbacks and disadvantages discussed in the background section of the subject application are inherent in the individual packaging technique disclosed in the Henniges reference. However, the inventive concept recited in rewritten independent claim 3 addresses the drawbacks and disadvantages of individually packaging components and instrumentation from product inventory by providing a self-contained kit including a spinal plate, bone screws and a screw driver instrument which are integrally contained and sealed within a common container to maintain a sterilized condition prior to the spinal surgery. For at least these reasons, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 3 as being anticipated by the Henniges reference.

In summary, the Applicant has demonstrated that none of the asserted patent references disclose each of the elements and features recited in independent claim 3. Accordingly, the Applicant requests allowance of independent claim 3 and the claims depending therefrom. Claims 5-9, 17, 20 and 22-26 depend from rewritten independent claim 3, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 3.

Additionally, further reasons support the patentability of these dependent claims. For example, claim 5 recites that the surgical kit further comprises an interbody implant adapted for disposition within an intervertebral space between the first and second vertebrae. However, the Henniges reference, which is the only reference which discloses a spinal plate, bone screws and a driver tool, fails to disclose or suggest the inclusion of any type of interbody spinal implant.

Claim 26 recites that the surgical kit includes “a template including a number of images corresponding to one or more select sizes of said spinal plate member, one of said template images corresponding to a size of said spinal plate member included with the surgical kit.” Dependent claim 26 was rejected as being anticipated by the Banick reference. However, as indicated above, the Banick reference clearly does not satisfy the elements and features recited in independent base claim 1. Moreover, the element 64, which has been asserted to comprise a “template”, is referred to in Banick as “instructions of use”. One of ordinary skill in the art would understand that “instructions of use” is a writing or document that sets forth a method or technique for using a particular component, and does not comprise “a template including a number of images” that correspond to select sizes of a spinal plate member, and with “one of the template images corresponding to a size of the spinal plate member included with the surgical kit”. Indeed, the Banick reference fails to disclose or suggest that the instructions of use 64 include images that correspond to select sizes of a spinal implant, with one of the template images specifically corresponding to the size of the spinal implant included with the surgical kit.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 3, 5-9, 17, 20 and 22-26.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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